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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,315	09/08/2000	Kathleen E. Rodgers	98.009-B1	3507

20306 7590 03/14/2002

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1653	3

DATE MAILED: 03/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/658,315	Applicant(s) RODGERS ET AL.	
	Examiner Anish Gupta	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2 and 31-44* is/are pending in the application.

4a) Of the above claim(s) *34-37 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) *1,2,31-33,38 and 40-44* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

The peptides corresponding to Seq. ID No. 2-18, and 20-39.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 31-44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with David Harper on 02-25-02 a provisional election was made with traverse to prosecute the invention of the species corresponding to SEQ. ID. No. 9. Claims 1-2, 31-33, 38, and 40-44 read on the elected species Affirmation of this election must be made by applicant in replying to this Office action. Claims 34-37 and 39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-2, 31-33, 38 and 40-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method is indefinite since the method does not indicate when to stop the contacting of the active agent. Applicants are requested to amend the claim to place the limitation "For a time and under conditions effective to augument erythropoiesis" to render the claim definite.

Claim 40 and 44 state the limitation "between about .1 ng/ml. . ." However it is unclear what are the lower and upper limits since between allows for only between the claimed range but about allows for outside the claimed range. Applicants are requested to delete either "between" or "about."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-2, 31-33, 38 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrug et al. in view of Pfeilschifter et al.

The claims are drawn to a method for augmenting erythropoiesis comprising contacting erythroid progenitor cells with an angiotensin II analogue.

Mrug et al. teach angiotensin II stimulates erythropoiesis and is mediated through its AT1 receptor (see page 2313). The binding of angiotensin II to AT1 receptor activates the Jak-2 kinase. Since AT1 receptors are present on erythroid progenitors, angiotensin II may stimulate erythroid proliferation directly and augment the effect of either the erythropoietin signal transduction pathway or that of other erythroid growth factors that share Jak-2 kinase mediated signal transduction pathways (see page 2313). The concentration of angiotensin II utilized was 100nM (See page 2311). The difference between the prior art and the instant application is that the reference does not teach the use of the peptide Asp-Arg-Val-Tyr-Val-His corresponding to Seq I.D. 4.

The reference of Pfeilschifter et al. teach that angiotensin II analog, Asp-Arg-Val-Tyr-Val-His, angiotensin (1-6) shows some affinity for the AT1 receptor (see page 61). The reference demonstrates the affinity angiotensin (1-6) through the stimulatory affects of the peptide on phospholipase D mediated via the angiotensin II AT1 receptor (see page 61). Therefore, since Mrug et al. teach that angiotensin II can induce erythropoiesis through the AT1 receptor, it would have been obvious to use the peptide Asp-Arg-Val-Tyr-Val-His to simulate erythropoiesis because this peptide also shows an affinity for the AT1 receptor.

As for the dosage claimed , generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Finally, for the treatment of anemia, such language is an intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-2, 31-33, 38 and 40-44 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,239,109. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The US Patent teach a method for augmenting erythropoiesis comprising erythropoid progenitor cells with a peptide corresponding to SEQ. ID. NO4. The sequence corresponding to SEQ. ID. NO 4 of the reference is identical to the peptide corresponding to SEQ. ID. NO. 4 of the instant application (see claim 1 of the US Patent and claim 2 of the instant application). Both, the Patent and the instant application, teach a similar dosage range and concentration range for the active agent (see claim 3-10 of the Patent and the claims 40-43 of the instant application). Thus the US Patent and the instant application sufficiently overlap it the subject matter and thus are not patentably distinct from each other.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta 2/24/02

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600